

Appl. No. 10/010,911

Reply to Office Action of June 14, 2004

**REMARKS**

Claims 31-46 were previously pending in the application, claim 40 was withdrawn and claims 31-39 and 41-46 were rejected. In response to Examiner's suggestion that all pending claims be canceled and that a new set of claims be filed beginning with number 47, claims 1-39 and 41-46 have been canceled, claim 40 withdrawn and new claims 47-60 have been added.

**CLAIM REJECTION UNDER 35 U.S.C. §103**

Examiner rejects claims 31-39 under 35 U.S.C. §103(a) as being unpatentable over Parker et al. in combination with Charms. Examiner states that Parker et al. teaches a device such as claimed except for the use of a coaxial cable and that Charms teaches the equivalence of coaxial and non-coaxial cables to transmit electrical signals in catheters. The Examiner concludes that it would have been obvious to the artisan to use a coaxial cable in place of the non-coaxial cable of Parker et al. since these are recognized equivalents in the art as taught by Charms, thus producing a device such as is claimed. Since Applicants' claims 31-39 have been canceled and replaced by new claims 47-60, the following remarks will be addressed to new claims 47-60.

Applicants describe an apparatus for delivering localized x-rays in a micro-environment such as an artery. A coronary artery after dilation by angioplasty has a diameter of only approximately 3 millimeters or less. Thus, Applicants' independent claim 47 specifically recites "... an x-ray source at the catheter distal portion, the x-ray source having a vacuum chamber defined by a chamber wall and containing an anode and a cathode for generating an electric field, the vacuum chamber having a diameter less than 3 millimeters; ...". The Parker et al. reference describes an x-ray micro tube used in the treatment of a patient with a tumor. Referring to column 9 lines 44-47, Parker et al. states that an x-ray micro tube of his design is

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made within a range of 1/8 inch to 1 inch and is preferably 1/4 inch. Thus, an artery into which Applicants' apparatus may be inserted for the purpose of delivering localized x-rays has a diameter smaller than the minimum dimension of the x-ray micro tube described in Parker et al.

The reduced dimensions of the x-ray apparatus increase the problems associated with electrical flashover which occur due to the generation of large electric fields. For example, an electrical field exists at the surface of the cathode while the outside of the vacuum housing is at ground potential. Applicants' claimed arrangement reduces flashover at the small dimensions by including an x-ray source, a vacuum chamber, an electrically insulating material, a flexible coaxial cable and a conductive layer as is specifically recited in Applicants' claim 47.

It would be insufficient to suggest that the dimensions of Parker et al. may simply be reduced since the Parker et al. arrangement operates at much higher voltages requiring liquid cooling due to generated heat. Reducing the dimensions of Parker et al. would only further increase the operating temperature of the device which in turn increases the probability of flashover. Thus, it would certainly not be recommended nor is it obvious to reduce the diameter of the micro tube in Parker et al. to less than 3 millimeters.

It is the combination of the electrical insulating material, the coaxial cable and the conductive layer that reduces the problems associated with flashover at diameters of 3 millimeters or less, thus also resulting in a highly manufacturable x-ray apparatus. The x-ray source which includes portions of the anode and the cathode are housed within a vacuum chamber. As claimed, an electrically insulating material is positioned between the vacuum chamber wall and the anode joints of the chamber wall. This electrically isolating material is effective in reducing flashover as the diameter of the x-ray apparatus is reduced to 3 millimeters or less. The flexible coaxial cable has a center conductor which is coupled to the anode of the

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apparatus and an external conductor. The center location of the conductor within the coaxial cable aligns with the anode connection, thus simplifying the coupling. Similarly, the external conductor of the coaxial cable surrounds the center conductor but is electrically separated from it by a layer of dielectric material. The location of the external conductor is positioned for coupling to the cathode. As claimed, the coupling is achieved by a conductive layer overlying a portion of the vacuum chamber coupled to the cathode and the external conductor of the coaxial cable. The conductive layer has a low profile, large conductive surface and simplifies contact in a small confined area.

Parker et al. even when taken in view of Charms, does not teach or suggest the specific combination of components recited in Applicants' new claim 47. As already stated, neither of the cited references teach an x-ray source at the catheter distal portion having a vacuum chamber defined by a chamber wall and containing an anode and cathode for generating electric field wherein the vacuum chamber has a diameter of less than 3 millimeters. They do not teach or suggest using a coaxial cable for contacting the anode and cathode allowing for high voltages to be provided in a low profile. Charms merely discloses the use of a coaxial cable for carrying electrical energy to a heart during defibrillation. The references do not teach or suggest an electrically insulating material positioned between the vacuum chamber wall and the anode at joints of the vacuum chamber wall. Finally, the references do not teach or suggest a conductive layer overlying a portion of the vacuum chamber. In view of the above, it can be only be concluded that Applicants' new claim 47 distinguishes over and is totally unobvious in view of the cited references taken singly or in valid combination.

New claims 48-54 are believed to properly depend, either directly or indirectly, from new independent claim 47 and are believed allowable therewith.

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Examiner rejects claims 41-46 under 35 U.S.C. §103(a) as being unpatentable over Parker et al. in combination with Charms as previously applied taken further in view Suzuki and Houston. Examiner states that Suzuki teaches boron nitride as a housing composition in an x-ray tube and that Houston teaches the equivalence of quartz and boron nitride as insulators. Examiner concludes that it would have been obvious to the artisan of ordinary skill to employ boron nitride in the housing of Parker et al. since these are equivalent as insulators as taught by Houston and since it is appropriate for an x-ray tube housing as taught by Suzuki. Since claims 41-46 have been canceled, Applicants' remarks with respect to this rejection shall be directed to Applicants' new independent claim 55 and dependent claims 56-60 which depend from independent claim 55.

Applicants new independent claim 55 specifically claims "... a catheter with a lumen ..., the catheter distal portion including an x-ray source, the x-ray source includes a cathode and an anode operating with an electric field of 20 keV/micron or less to prevent flashover; a housing for the x-ray source having a diameter of 3 millimeters; ...". As previously explained, Parker et al. neither teaches nor suggests dimensions of the type specifically claimed by Applicants. Furthermore, Applicants specifically recite in independent claim 55 a cathode and an anode operating with an electric field of 20 keV/micron or less to prevent flashover. To reduce this magnitude would reduce the effectiveness of the x-ray apparatus. Parker et al. employs a conventional filament cathode which must operate at voltages higher than 20 keV to produce a useful radiation magnitude, even in the 8-10 keV range. Thus, it is respectfully submitted that Parker et al. does not teach or suggest the features recited in Applicants' new claim 55. Furthermore, neither Charms, Houston nor Suzuki supply the deficiencies pointed out above with respect to the Parker et al. reference. It is therefore respectfully submitted that

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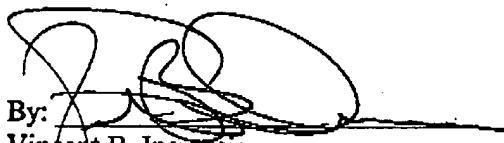
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Applicants' new independent claim 55 distinguishes over and is unobvious in view of the cited references taken singly or in any valid combination, and therefore claim 55 is allowable. Claim 56-60 are believed to properly depend, either directly or indirectly, from Applicants' new independent claim 55 and are believed allowable therewith.

Accordingly Applicants respectfully submit that the application, as amended, is now in condition for allowance, and such allowance is therefore earnestly requested. Should the Examiner have any questions or wish to further discuss this application, Applicants request that the Examiner contact the Applicants' attorney at 480 385-5060.

If for some reason Applicants have not requested a sufficient extension and/or have not paid a sufficient fee for this response and or for the extension necessary to prevent abandonment on this application, please consider this as a request for an extension for the required time period and/or authorization to charge Deposit Account No. 50-2090 for any fee which may be due.

Respectfully submitted,

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